

REMARKS

Claims 1 and 3-7 are pending in the present application.
Claim 2 was previously canceled.

1. Rejection of claim 1 under 35 U.S.C. §102(b)

The Official Action states that claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Hoffmann (U.S. Patent No. 5,820,876). In particular, the Official Action in relevant part states that:

The claimed invention is a patch comprising a backing layer and an adhesive layer that is disposed on the backing layer. The adhesive layer is compounded with a drug and an adhesive base agent. The adhesive base agent comprises: (i) styrene-isoprene-styrene block copolymer, (ii) 2-ethylhexyl acrylate-vinyl acetate copolymer, and (iii) a basic nitrogen-including polymer, which includes a basic nitrogen and has no adhesion property at normal temperature selected from the group consisting of methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate.

Hoffmann teaches a transdermal therapeutic system for supplying active substances to the skin. The active substance reservoir matrix can be a rubber material such as styrene-isoprene-styrene block copolymer. Adhesive materials including a self-crosslinking acrylate copolymer, e.g. of 2-ethyl-hexyl acrylate, vinyl acetate and an acrylic resin of dimethylaminoethylmethacrylate and neutral methacrylate (EUDRAGIT E 100 from ROHM) are disclosed.

Therefore, the limitations of claim 1 are anticipated by the teachings of Hoffman.

Applicant respectfully traverses this rejection of claim 1. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully direct the Examiner's attention to the full scope of claim 1. Of particular relevance to the instant rejection is the fact that the following components are present in one layer of the claimed patch:

- (a) a drug;
- (b) styrene-isoprene-styrene block copolymer;
- (c) 2-ethylhexyl acrylate-vinyl acetate copolymer; and
- (d) a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate-butyl methacrylate-

dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate.

In contrast, the Hoffmann reference discloses patch formulations containing separate and distinct layers. In particular, the Hoffmann reference describes patch formulations which contain an active substance distribution device (i.e., a reservoir matrix layer) and a separate and distinct fixing device (such as, a porous pressure sensitive adhesive layer). The Hoffmann reference does not describe the combination of components (a)-(d) in a single layer of the embodied patch formulations as required by presently pending claim 1. Further, the Hoffmann reference fails to disclose the specific layer structure of the patch formulations as recited in presently pending claim 1. Accordingly, the Hoffmann reference cannot anticipate presently pending claim 1, because the cited reference does not describe each element arranged as recited in the claim, as required by In re Bond.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 1.

2. Rejection of claims 1 and 3-7 under 35 U.S.C. §103(a)

The Official Action states that claims 1 and 3-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over

Miranda et al. (U.S. Patent No. 5,656,286), in view of Hoffmann.

In particular, the Official Action in relevant part states that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a transdermal drug delivery composition with styrene-isoprene-styrene block copolymers as rubber-based pressure-sensitive adhesives and butyl methacrylate that is copolymerizable with methacrylic acid and dimethylaminoethyl methacrylate as suggested by Miranda, combine it with the transdermal composition with styrene-isoprene-styrene block copolymer, copolymer of 2-ethyl-hexyl acrylate and vinyl acetate, and an acrylic resin of dimethylaminoethylmethacrylate and neutral methacrylate (EUDRAGIT E 100 from RÖHM), as suggested by Hoffmann, and produce the instant invention.

Applicants respectfully traverse the rejection of claims 1 and 3-7. The cited references do not establish a *prima facie* case of obviousness against the presently pending claims. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U.S. (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the

marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, supra, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ 1016, 1023 (C.C.P.A. 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A. The Presently Claimed Invention

The presently pending claims as exemplified by presently pending independent claim 1 are directed to:

A patch comprising a backing layer and an adhesive

layer disposed on the backing layer and compounded with a drug and an adhesive base agent, wherein the adhesive base agent comprises styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate - vinyl acetate copolymer and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate - butyl methacrylate - dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate.

Dependent claims 3-7 incorporate the features recited in independent claim 1, and further recite the features of: the drug, pergolide; the use of an organic acid in the adhesive layer; the use of an alicyclic saturated hydrocarbon-based tackifier in the adhesive layer; and the weight ratio of the content of the styrene-isoprene styrene block copolymer to the content of the 2-ethyl-hexyl acrylate vinyl acetate copolymer, respectively.

B. The Teachings of the Miranda et al. Reference

The Miranda et al. reference describes "a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition." See Miranda et al., column 1, lines 26-28.

C. The Teachings of the Hoffmann Reference

The Hoffmann reference describes "a novel therapeutic

system with active substance depot for the administration of the active substance." See Hoffmann, column 2, lines 37 and 38.

**D. No *prima facie* Case of Obviousness has Been Shown by the
Examiner**

Neither the Miranda et al. nor the Hoffmann references, taken alone or in combination, disclose all of the limitations of the presently pending claims, as required by In re Wilson. In particular, the Examiner asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a transdermal drug delivery composition with styrene-isoprene-styrene block copolymers as rubber-based pressure-sensitive adhesives and butyl methacrylate that is copolymerizable with methacrylic acid and dimethylaminoethyl methacrylate as suggested by Miranda, combine it with the transdermal composition with styrene-isoprene-styrene block copolymer, copolymer of 2-ethyl-hexyl acrylate and vinyl acetate, and an acrylic resin of dimethylaminoethylmethacrylate and neutral methacrylate (EUDRAGIT E 100 from RÖHM), as suggested by Hoffmann, and produce the instant invention." See page 5 of the Official Action. However, neither the Miranda et al. nor the Hoffmann

references describe or suggest a single layer containing the combination of components required by the patch formulations of the presently pending claims. In particular, neither of the cited prior art references taken alone or in combination describe an adhesive layer containing a drug; styrene-isoprene-styrene block copolymer; 2-ethylhexyl acrylate-vinyl acetate copolymer; and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate.

Further, the Hoffmann reference teaches away by disclosing patch formulations where the layer structure and the combination of components in the layer(s) are different from those recited in the presently pending claims.

As such, the Examiner has provided no reason to combine the known elements in the fashion claimed by the applicants. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

3. Provisional Rejection of Claims 1 and 4-6 under the
Judicially Created Doctrine of Obviousness-Type Double Patenting

The Official Action states that claims 1 and 4-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending U.S. Patent Application Serial No. 10/526,065.

The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other. The Examiner notes that the instant claims are directed to a patch comprising a backing layer and an adhesive layer that is compounded with a drug and an adhesive base agent. The Examiner asserts that the claims of the co-pending application no. 10/526,065 also describe a patch comprising a backing layer and an adhesive layer compounded with an adhesive agent and pergolide.

It is submitted that present claims 1 and 4-6 are patentably distinct from the claims of co-pending application no. 10/526,065. With regard to claims 1 and 4-6 of the instant application, all of claims 1 and 4-6 are directed to a patch formulation where the adhesive layer contains a drug; styrene-isoprene-styrene block copolymer; 2-ethylhexyl acrylate-vinyl

acetate copolymer; and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate. Claims 1-11 of co-pending application no. 10/526,065 do not recite the specific combination of components in the adhesive layer that are required by pending claims 1 and 4-6 of the instant application. Accordingly, present claims 1 and 4-6 are patentably distinct from claims 1-11 of co-pending application no. 10/526,065. The Examiner is respectfully requested to withdraw this rejection of pending claims 1 and 4-6.

CONCLUSION

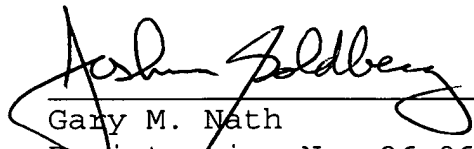
Based upon the above remarks and amendment, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and allow all pending claims 1 and 3-7 in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,
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